TESTIMONY OF

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ARONOFF ASSOCIATES
NEW YORK, NEW YORK

HEARING ON

PRODUCT LIABILITY REFORM

IN THE

SUBCOMMITTEE ON
TELECOMMUNICATIONS, TRADE AND CONSUMER PROTECTION
COMMITTEE ON
COMMERCE
U.S. HOUSE OF REPRESENTATIVES

APRIL 8. 1997

Our independent analysis of the current biomaterials supply situation for permanent medical implants is based on the following methodology:

We focused on suppliers of four materials used for permanent implants. The supply status of three of these materials:

- polyester yarn made from polyethylene terephthalate (PET), [known as DuPont's Dacron"],
- polytetrafluoroethylene (PTFE), [known as DuPont's Teflon"'] and
- polyacetal [known as DuPont's Delrin® and Hoechst Celanese's Celcon"]

was originally tracked in our earlier study, just after DuPont exited the market. The current study also includes ultra high molecular weight polyethylene.

We contacted 23 materials supplier companies and separate divisions of companies that supply one or more of these materials, to determine their policies on supply for permanent medical implants. Where there was a company-wide policy in place, the results from the separate divisions handling each material were counted as one company. Occasionally, the policies of different sections of the same company were different. These were counted as separate companies. In some cases. the companies contacted were totally unresponsive. We did not count them. The individuals in responsive companies were all knowledgeable of their companies' policies on this matter, and some participated in forming them. We used a formal materials supplier questionnaire to structure our discussions to the extent of eliciting answers to key questions that could be quantified, along with a less formal conversational approach in order to obtain the supplier's point of view and to give us the flavor of the concerns and approaches that were behind current company policies. In most cases the respondents wanted their identities held confidential. Often they did not wish their responses, including whether they were willing to consider supplying this market, to be specifically associated with their companies. In other cases, some supplier companies did not mind being identified with their policies or even quoted. Because of the relatively limited number of independent suppliers for most of the materials discussed in our study, we did not generally associate specific answers with companies in order to preserve anonymity.

We also contacted 17 manufacturers of medical implants. We used a formal questionnaire to structure our discussions to the extent of eliciting answers to key questions that could be quantified along with a less formal conversational approach in order to obtain an overall view of the implant manufacturer's supply status. Again, almost all of the participants requested anonymity and confidentiality as to the source of our information, Without agreeing to these conditions, very little. if any. information would have been obtained on the current materials supply situation of implant makers.

Background

Prompted by the withdrawal of E.I. du Pont de Nemours and Co. (DuPont) as a supplier of key materials to permanent medical implant manufacturers, HIMA in 1993 commissioned ***Market Study: Biomaterials Supply for Permanent Medical Implants*** to develop an understanding, from the perspective of the materials supplier, of the principal factors that operate in this market. That study depicted a materials supply situation that was then in turmoil and suggested shortages of essential materials in the longer term Since then many major as well as smaller suppliers have prohibited the sale and use of their materials for implant purposes or have imposed highly restrictive conditions on such sales, apparently to avoid exposure to costly and possibly catastrophic lawsuits. There is a need to understand how this apparently unreliable supply situation is affecting the implant industry and the patients and doctors it serves, and the current position of materials suppliers. The following study depicts and analyzes the current biomaterials supply situation from the perspective of the materials suppliers and the implant manufacturers.

Objectives of the Study

The major objectives of the study, Mr. Chairman, were to:

Identify and analyze, from the material supplier's perspective. the key factors that govern current policies on supply of materials to manufacturers of permanent medical implants and determine the basis for these policies.

To document the current effects of material supplier policies on the implant industry by following its effects on the supply of PET polyester yarn, polytetrafluoroethylene (PTFE), polyacetal resin and ultra high molecular weight polyethylene (UHMWPE).

- To forecast what the effects of the current materials supply situation might be on patients requiring permanent implants and the doctors that use them

- To forecast how the current materials supply situation will affect the medical implant industry itself.

Findings

Mr. Chairman, our findings were as follows:

Key Factors Governing Current Supplier Policies on Supply for Permanent Implants
Of material supplier companies surveyed only 25% (down from 42% in 1993) are currently supplying or willing to consider supplying implant manufacturers. The remaining 75% are not willing to supply this market. In deciding to sell or not to sell into this market, risk of legal liability was a key factor for 100% of suppliers, small market size was a key factor for 60% of suppliers. Humanitarian concerns were clearly a key factor for 10% of suppliers and perhaps as many as 25% of suppliers. Although all of the companies to which humanitarian concerns can be attributed in any degree are currently

supplying the market, most (80%) have highly restrictive policies that generally limit sales to financially powerful companies that can back indemnification agreements, provide high levels of liability insurance coverage (e.g. $100 million) or have high levels of ready cash (e.g. $100 million). Some suppliers require that potential implant maker clients have sales of at least $1 billion, In addition, test results, demonstration of appropriate use of the material, FDA and other regulatory approvals, a demonstration of the ability to do testing for FDA compliance and a clean FDA record may be part of the requirements for sale.

Such protective measures taken by supplier companies are based on their analysis of DuPont's experience with Vitek. DuPont sold Vitek about $0.05 worth of PTFE Teflon" per temporo-mandibular joint implant, totaling a few hundred dollars per year. DuPont had nothing to do with the design, manufacture or sale of the implant. In the face of mass litigation due to problems with its implant Vitek went bankrupt. This left DuPont as the "deep pockets" to confront multiple lawsuits. DuPont has successfully defended itself in hundreds of cases in 42 states at an estimated cost of $8 million per year.

The financial protections of supplier agreements deliberately limit sales to large powerful companies that are unlikely to go bankrupt under assault by multiple lawsuits. Another factor in the DuPont - Vitek scenario which suppliers consider significant is that the small implant maker apparently did not carry a level of liability insurance adequate to satisfy the demands of the plaintiffs. In addition, they believe the small implant maker did not use the supplier's material appropriately and did not properly test its product. Supplier experts who studied the case, believe Vitek did not fully comply with FDA regulations. Most companies, however, choose to follow DuPont's lead and avoid sales to implant manufacturers entirely.

Current Effects of Material Supplier Policies on the Implant Industry

Supply of PET Polyester Yarn

PET polyester yam is used to make the fabrics by which implants (e.g. heart valves) can be sewn to tissue and it is widely used for sutures and artificial blood vessels. Implant sales account for 0.002% of the worldwide polyester yarn market. Although there are about 150 polyester yarn manufacturers worldwide, if the United States pattern holds, we estimate that probably not more than 25% make their own PET resin and are thus completely independent. Such independent companies tend to be multinational industrial giants having sizable assets in the United States. They are thus sensitive to liability risk. Companies that do not make their own PET resin for conversion to yarn usually must conform to the policies of the resin supplier with regard to implants,

Of the implant companies surveyed that are major users of PET polyester, 67% were relying exclusively on stockpiled material purchased before DuPont finally let? the market to manufacture their products. None of the companies relying on stockpiles has a qualified alternate supply source to date. The companies that have alternate sources and are not working from stockpiles are part of large financially powerful companies.

currently provide materials that meet orthopedic implant industry standards

Montell which supplies about 10% of the resin consumed by the United States orthopedic implant industry announced its withdrawal from this field about one year ago due to liability concerns. Subsequently, they were persuaded to remain a supplier and have done so under stringent financial conditions to protect themselves against liability. Hoechst Celanese continues to be the major supplier of UHMWPE to the orthopedic implant industry. As they are concerned about high liability risk their policy may change. In a letter to Senator Joseph I. Lieberman, dated 2/14/97, D.R. Greeley, Vice President, Government Relations for Hoechst Celanese wrote "....inasmuch as this application's product liability risks are extremely high - Hoechst Celanese may, in the future, be forced to exit this market segment absent biomaterial supplier protections."

UHMWPE **Fiber: A** unique high strength material used in orthopedic surgery. It is produced by perhaps three industrial giants worldwide. A product based on it that provides special benefits to patients compared to other materials will disappear from the market when its stockpile runs out by the end of this year. The level of indemnification required by the supplier did not make sense to the implant maker in view of the low volume of this product. Other suppliers will not sell into the United States market.

Effects on Patients and Doctors

Based on our survey of implant makers, implants have continued to be supplied to the market in a normal manner largely because manufacturers can draw on stockpiles of unique materials that they are no longer allowed to purchase on the open market. In a sense it is like the biblical story in which seven years of grain were stored to support the population during seven lean years. The population did not feel the effect of the grain shortage at first during the lean years because bread was produced from stockpiles. Currently there has been little or no effect on the supply of lifesaving, life enhancing implants because companies have continued to manufacture from stockpiles and some companies have obtained some materials from alternate suppliers. Rather than producing dramatic results, the consequences of this shortage are insidious but nevertheless real.

We foresee a narrowing of choices for doctors over the next five years in providing the best treatment for patients because some implant products will disappear entirely from the market. Other products will remain on the market, but will be made from "good" available materials rather than the "best" materials that have become unavailable due to depletion of stockpiles. Products that disappear entirely may be made from unique materials that are available from only one supplier that withdrew from the market or will not sell to smaller manufacturers. In some cases, the market volume of such products may not justify meeting the conditions imposed by the supplier for protection against liability. Depending on the material, stockpiles may reportedly last from eight months to ten years. The descent from the "best" to the "good" is in progress and will accelerate as stockpiles of the "best" are depleted.

Mr. Chairman, my analysis of what will happen to the medical implant industry itself is as follows:

innovative products, will be crippled due to an inability to obtain materials. Start-ups that require materials that have been restricted for implant use will be unable to enter the market as independent companies, if at all.

While United States companies must confront the above problems, their overseas counterparts do not face similar problems and are sometimes supplied by companies that place restrictions on supply to the United States market.

Conclusion

As a part of the research for this report, Mr. Chairman, Mr. John A. Krol president and CEO of DuPont was questioned on his company's policies regarding supply of materials for permanent implants and under what conditions it would be reconsidered. Mr. Krol stated that if and when legislative proposals to protect suppliers of materials used in implants are passed, DuPont would again supply the implant industry Many other supplier companies would probably do the same. In our survey. we found appropriate legislation would have a positive effect on the willingness of 40% of companies surveyed to supply the implant market.

In conclusion, I would like to point out that one executive at an implant company described the current supply situation to me as "like a war." One can only wonder, Mr. Chairman, if it serves the larger public good to have the supply lines in the war against premature death and disability under constant attack,

TESTIMONY OF

BELINDA SIMONINI
MOTHER OF TITUS SIMONINI

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Titus: "Testing 1,2,3,4,5,6,7,8,9,10 Testing, it works Mom"
Belinda: "Introduce yourself honey"
Titus: "Hi, my name is Titus. I live in San Diego and I have a shunt in my head, my Mom is going to tell you about it."

Belinda: "Hi, I'm Belinda Simonini, Titus' Mom, and I am very thankful to have him standing here with me today! Titus is a very happy, smart and active little boy but he had a very difficult start in life as he was born with Hydrocephalus, a congenital defect that affects approximately one in 500 children, and is more commonly known as "water on the brain". This "water" is actually Cerebral Spinal Fluid that our bodies normally produce, circulate throughout the spine and the brain and then reabsorb. When Hydrocephalus occurs there is too much of this fluid collecting in the ventricals of the brain, exerting pressure on the brain itself and causing harm to all of the brains' functions. Titus has a Delta Valve Shunt, like this one, manufactured by P.S. Medical. Shunt surgery is the most common operation in most neurological centers, and in pediatric centers, half of the procedures involve shunts. The shunt has a small valve which regulates the flow of fluid between the ventricle into which it's inlet tubing is inserted and the outlet tubing which takes the excess fluid to another site in the body for reabsorbtion. In Titus' case his tubing runs to his abdominal cavity. The shunt works very well and has given Titus the ability to live the normal life that he has today.

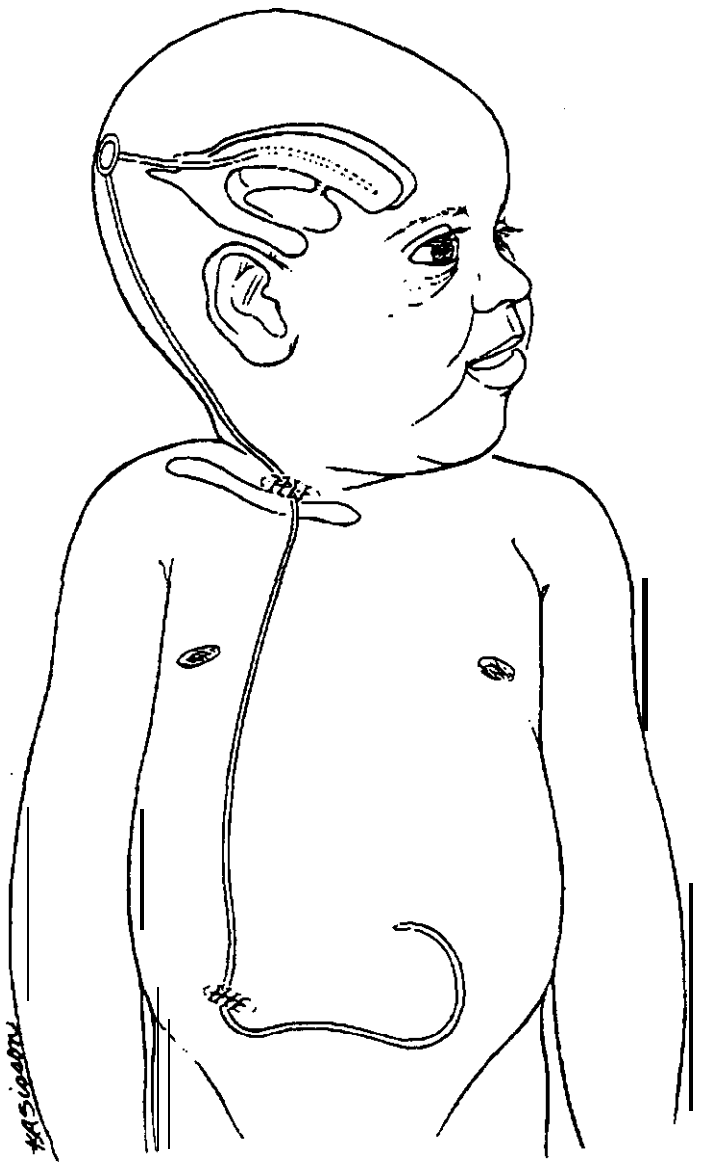
When Titus was born, the excess fluid in his brain had compressed his brain matter so severely that it appeared that he did not have all of his brain and that it was possibly not even structurally sound. With great urgency, his neurosurgeon, the late Dr. Prioleau of Kaiser, placed a shunt in his five pound body to drain the damaging fluid from his brain. Even with this treatment we were told that the extreme pressure had probably caused gross damage and to expect a child with few motor and mental capabilities, impaired vision and more. Six weeks after the surgery, when we took Titus back for an MRI, we found that his brain was all there and had rebounded completely. The shunt had worked phenomenally well! Now Titus had a chance to catch up and work towards developmental milestones with the aid of this device. Three years later the results are a true blessing, Titus is as bright, or more so, than the average three year old. It is a joy to take Titus anywhere where he will meet new people as he truely enjoys talking with them. We are always questioned as to how old he is because of his small frame coupled with his large vocabulary and inquisitive questions, and we sometimes refer to him as "walkie talkie". Titus will *enjoy* pursuing his gift for music and other normal activities in regular schools. Titus is really now healthy and strong and knows no limits. I credit God's good will and medical technology for his miraculous recovery.

The lifesaving shunts and the surgeons who are able to successfully implant them are what make lives like Titus' possible for the hundreds of thousands of people in our country who rely on a shunt. Before the 1950's most children died of this heartbreaking condition. Without effective shunts their heads filled with fluid and grew to grotesque proportions sometimes even beyond the size of a basketball. These children quickly suffered from severe headaches, vision loss then blindness and eventually all of the disabilities from a severly damaged brain and finally death. In the early 1950's silicone was first used in a new design created by John Holter, a father of a son with Hydrocephalus. The new silicone shunts worked much better and today the over 100 types of shunts available are all composed of and coated in hard silicone, very different from liquid silicone, products. This silicone is very expensive to produce and is made primarily by one company. Altemacive sources will be very difficult to find and the shunts will become unavailable without the silicone.

Shunts are the only viable treatment for the vast majority of Hydrocephalus patients, even so they hold the risk of occasional malfunction, blockage or infection. Titus will need another shunt at some time, as will the next baby born with hydrocephalus and the next premature baby that develops the need for a shunt as well as many accident and stroke victim's who will need a shunt to survive and recover. We as a society need to be sure that a shunt is available to all of these children and adults. As a mother, I am thrilled for Titus' miraculous health and prospects for the future but am terrified of the freighttrain of unbridled and misdirected litigation that threatens to eliminate the sources of silicone for the shunts to be made. Without a shunt our wonderful little boy would suffer a slow and painful deterioration leading to a heartbreaking death.

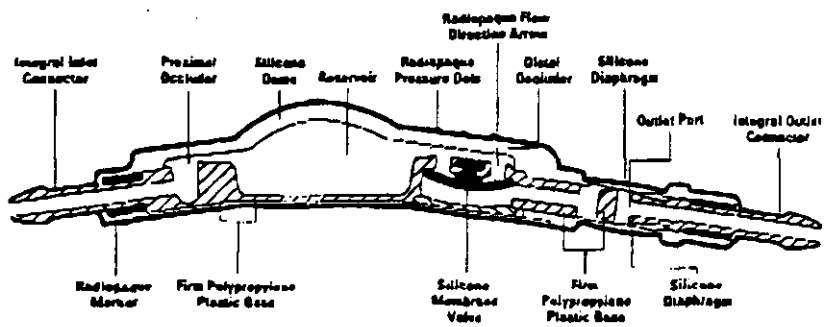
Titus is not alone, Jeffery Liakos, Mark Stephens, Tara Randsom and so many other children and adults live fruitful, active lives which should not be compromised, ever, by a shortage of shunts. There are over seven and a half million Americans as well that rely on implants to save and enhance their lives. These implants are as far ranging as simple sutures, tubing, and repair patches routinely used in surgery to Diagnostic Cardiac Cathereterization to state of the art pacemakers, heart valves, intraocular lens for cataract patients, stimulators for bone growth, finger, knee and hip replacements and more which all require some type of biomaterial such as the special types of polyester, silicone, nylon, PTFE, polyurathane and polyethylene which are all at risk of becoming unavailable.

Reform is desperately needed to protect these biomaterial suppliers. Biomaterials legislation - which will not impair legitimate lawsuits and damages for faulty implantable devices - is before you. I urge you to support the Biomaterial Access Assurance Act and not allow lives like Titus' to be compromised! Titus might like to say something in closing." (Titus might, hopefully, sing "Take me out to the ballgame" and say goodbye.)



PS Medical®

Delta™ Valve



Remains Closed in Response to Negative Hydrostatic Pressure